

Notice of Allowability	Application No.	Applicant(s)	
	10/524,304	SANDERS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/22/07.
2. ☒ The allowed claim(s) is/are 1,2,4-6,8,10,11 and 14-34.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Status of the Claims

1. Claims 1-2, 4-6, 8, 10, 11 and 14-34 are pending.

Applicants' amendment filed May 22, 2007 is acknowledged. Applicants' response has been fully considered. Claims 1 and 29-34 have been amended, and claims 3, 56 and 57 have been cancelled. Therefore, claims 1-2, 4-6, 8, 10, 11 and 14-34 are examined.

Withdrawn Informalities

2. The previous objection to the specification is withdrawn in view of applicant's amendment to the specification in the amendment filed May 22, 2007.

Withdrawn Claim Objections

3. The previous objection to claim 3 is withdrawn in view of applicant's cancellation of the claim in the amendment filed May 22, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 29-34 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims, and applicants' response at page 7 in the amendment filed May 22, 2007.

Withdrawn Claim Rejections - 35 USC § 102/103

5. The previous rejection of claims 1-2, 4-6, 8, 10, 11, 14-34, 56 and 57 under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious

over Suskine *et al.* (US 2005/0074466) is withdrawn in view of applicant's amendment to the claims, and applicants' cancellation of the claims, and applicants' response at page 7 in the amendment filed May 22, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Omri M. Behr on June 1, 2007.

Examiner's Amendment to the Specification:

Please replace the paragraph at page 1, lines 6-7 with the following paragraph:

This application is a 371 of PCT/US03/25708 filed August 18, 2003, which claims priority of United States Provisional Application Serial number 60/404,378 filed August 19th 2002.

Examiner's Amendment to the Claims:

Claims 1, 16, 17, 21 and 24-28 have been amended as follows:

1. (Currently amended) A method of treating a condition related to holocrine gland dysfunction in a patient having excess levels of secretions from holocrine glands, the method comprising administering a secretorally-reducing an effective amount of a botulinum toxin to a ~~the patient having excess levels of secretions from holocrine glands,~~ wherein said excess levels of glandular secretion result in the conditions which are selected from the group consisting of; seborrheic dermatitis, rhinophyma, seborrhea, seborrheic blepharitis, and sebaceous cysts, whereby the excess levels of glandular secretions in said patient is ~~are~~ reduced.

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16. (Currently amended) The method of claim 6 comprising the subdermal injection of the botulinum toxin at multiple sites in the skin, wherein the amount injected is between 1 and 100 U of the botulinum toxin.

17. (Currently amended) The method of claim 16 wherein the amount injected is between 1 and 10 U of the botulinum toxin.

21. (Currently amended) The method of claim 24 wherein the amount injected is between 2 and 3 U of botulinum toxin A.

24. (Currently amended) The method of claim 20 wherein the amount injected is between 1 and 10 U of botulinum toxin A.

25. (Currently amended) The method of claim 17 wherein the amount injected is between 2 and 3 U of the botulinum toxin.

26. (Currently amended) The method of Claim 1, wherein said ~~method~~ administering is repeated periodically to inhibit the recurrence of undesirable levels of secretion.

27. (Currently amended) The method of Claim 26, wherein said ~~method~~ administering is repeated at intervals from about 3 months to about 6 months to inhibit said recurrence.

28. (Currently amended) The method of Claim 27, wherein said ~~method~~ administering is repeated at intervals of about 4 months to inhibit said recurrence.

The following is an Examiner's Statement of Reasons for Allowance: The following reference appears to be the closest art to the claimed invention. Suskine *et al.* (US 2005/0074466) teach the use of a botulinum toxin (i.e., serotype A, B, C, D, E, F, G) to treat acne, which the pathology centers on the pilosebaceous follicle comprising the sebaceous gland, the follicle (pore) and the vellus hair, and the treatment may be repeated periodically to inhibit the recurrence of acne, typically at intervals between about 3 months and about 6 months. However, the reference does not teach using a botulinum toxin in treating a patient having a condition of seborrheic dermatitis, rhinophyma, seborrhea, seborrheic blepharitis or sebaceous cysts. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK
May 31, 2007